UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	File No. 15-MD-2666 (JNE/FLN)
	January 24, 2019
	Minneapolis, Minnesota
	Courtroom 9E
	10:00 a.m.

THE HONORABLE DAVID T. SCHULTZ
UNITED STATES MAGISTRATE JUDGE

(MOTIONS HEARING)

APPEARANCES

FOR THE PLAINTIFFS:

MESHBESHER & SPENCE
Genevieve M. Zimmerman
1616 Park Avenue
Minneapolis, MN 55404

FOR THE DEFENDANTS 3M:

BLACKWELL BURKE P.A.
Mary Young
431 South Seventh Street
Suite 2500
Minneapolis, MN 55415

Court Reporter:

MARIA V. WEINBECK, RMR-FCRR
1005 U.S. Courthouse
300 South Fourth Street
Minneapolis, Minnesota 55415

Proceedings recorded by mechanical stenography; transcript produced by computer.

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P R O C E E D I N G S

(10:02 a.m.)

THE COURT: Good morning, everyone. Please be seated.

All right. Good morning. We're on the record in the matter of In Re Bair Hugger Forced Air Warming Devices Products Liability Litigation, MDL number 15-2666. Counsel for the plaintiff, if you would note your appearance for the record, please.

MS. ZIMMERMAN: Good morning, Your Honor. Genevieve Zimmerman for the plaintiffs.

THE COURT: Good morning, Ms. Zimmerman. And for the defendant?

MS. YOUNG: Good morning, Your Honor. Mary Young for the defendant.

THE COURT: Good morning, Ms. Young. All right. I have read everything that's been submitted. I'm familiar with the issues so just keep that in mind. Before we start, I just want to let you both know not related to this motion, obviously, I have a draft of the completed categorization order that I will hope to circulate if not today then tomorrow for further comments by everyone, so just a housekeeping matter.

Okay, Ms. Zimmerman, if you want to proceed.

MS. ZIMMERMAN: Thank you, Your Honor.

Good morning, and may it please the Court. We're here today on Plaintiffs' Motion to Compel Supplemental Discovery Responses pursuant to Rule 26(e). And as the Court is aware, Rule 26 requires that parties who have made disclosures have to supplement those disclosures to the extent that they learned that they are either incomplete or incorrect, if that information has not been made available or known to the other party during the course of discovery. And that's not particularly controversial.

Frequently, we're in front of this Court even on this case about plaintiffs' obligations with respect to updating plaintiff fact sheets, for example. Certainly, as we approach trials, there are additional medical records and other kind of details that are learned about in a particular case but that obligation is not unilateral. It is not only upon the plaintiffs to provide supplemental discovery responses to the extent that plaintiffs learn that there are either incompletions or inaccuracies in the productions that have been made up to the point with respect to previous discovery answers.

And to set the stage just a little bit, and this is one of the reasons that the motion that we filed with the Court includes a great many documents that the Court may or may not have had a chance to read. I appreciate it's a voluminous submission, but as a reminder about what this is,

we are not here in a single event case where there would still be a duty to supplement on both sides.

But we are here, of course, with respect to an MDL that involves right now over 5,000 cases. And the defendants make a number of points during their responsive motion opposing or responsive papers opposing this motion saying, of course, general causation discovery was bifurcated and that that closed back in 2017, just about two years ago. But as of March of 2017 there were only 1580 cases in this MDL and right now, of course, there are more than 5,000. The plaintiffs that have filed their cases since the time of the general causation discovery cut-off did not consent to an abrogation of the Federal Rules of Civil Procedure.

And so the other thing I think that is particularly important as we talk about kind of what is happening in this case is really to think about what's going to happen later today. Today the defendants are going to bring a motion for reconsideration of Daubert on general causation based on new information, and yet at the same time they walk into this Court, and they say that they don't have a duty to supplement discovery. That cannot be the rule. That's not the way the Federal Rules operate. That is not the way it ought to operate.

But I will say that over the course of the past

several years, it's clear that the defendants will not, will not supplement their discovery productions voluntarily because they think that this Court is not going to make them. That's ultimately what they think is going on here.

So we cite a number of cases in our papers, and I will say that with respect to I mean, for example, excluding and this is in the *Iweala v. Operational Tech Services* case, which is out of the District of Columbia in 2010. The Court there properly finds that excluding documents from production that are created after the close of discovery from a duty to supplement would encourage parties to wait until after discovery has closed to create documents containing potentially damaging information.

That's a policy that we don't want to encourage, and it's particularly important for a lot of different folks that may or may not have cases pending that are going to be governed by Minnesota law. And we've had choice of law briefing on a couple of different cases, but there are a number of different plaintiffs here who have claims that we believe are going to be governed by Minnesota law.

Now, why does that matter? Well, under Minnesota law and, specifically, the case is, I believe, *Stryker v. Mack, Mack v. Stryker Corporation,* I'm sorry. It's 748 F.3d 845. That's out of the Eighth Circuit in 2014. And the Eighth Circuit notes that defendants have a duty to test and

investigate their products based upon the foreseeable risk of harm to potential users in the light of current medical knowledge and discoveries. Further, the Eighth Circuit says manufacturers are held to the skill of an expert in the field that their products enter, and they are obligated to keep informed of medical knowledge and discoveries in that field.

Why does that matter? Well, Judge, it matters because we know that competitors, and I would point the Court to document, and I will say that I don't think that this was actually an exhibit, but I'm happy to provide a copy to the Court, Bates document number 3MBH00932516. It's a document from a competitor from 1993. The competitor is Gaymar Industries, and it's important because they use their forced air warming technology in connection with the Bair Hugger blanket. And what do they say under caution? They say convective air flow can cause airborne contamination to open wounds if they're not covered. This has been a warnings case. Now that information has not been presented to a trier of fact yet, but it is a warnings case.

Likewise, the actual product that was manufactured by Augustine Medical, there's a, if the Court has seen it, there's a disposable blanket and there's essentially like a cardboard fitting as between the hose and the cardboard blanket. In the early 1990's, Augustine Medical says right

on this and, again, this is Bates number 3MBH00500237. And it says, "Do not use the 200 series warming units in the OR. Thermal injury and airborne contamination may result."

Likewise, we know from evidence introduced and part of the motion today, a competitor in the forced air warming industry right now, Stryker, they developed and market the Mistral, they warn about airborne contamination. All of that matters because there is an obligation to do testing and to provide warnings to the doctors and the ultimate users, the patients as well, but these documents have not been produced to us. And up to this point, the defendants continue to deny that this is knowledge that they have.

We know from the Bair Paws document that is the subject of much litigation and, unfortunately, is still under seal by this Court, the defendants have acknowledged at least as of 2005 and 2007 and 2009 that the use of Bair Hugger can be contraindicated, contraindicated, in orthopedic surgery because it increases particles, because it increases the risk of nosocomial infection and transmission of pathogens in a hospital. These are all important admissions.

And from the plaintiffs' perspective, what Gaymar knows, what Stryker knows, what Augustine knew in the early 1990's is absolutely relevant to what warnings are provided

on the device here today in 2019. And because these issues about warning continue to be hard fought in this litigation and defendants continue to say, well, we didn't know about this, it's not a reasonable warning, but they're not supplementing with what they're doing. They either did the testing and haven't produced it or they didn't do the testing and then they need to stipulate that the testing has never been done.

THE COURT: Let me interrupt you for a second. You're not arguing, I don't think, that documents that would be responsive to what you're saying that existed prior to March of 2017 weren't produced. I mean that's not your motion, correct? You're saying anything that they've either created or come into possession of from March 2017 forward.

MS. ZIMMERMAN: Yes, Your Honor, as in pretty much any case, a plaintiff kind of plays a legal claim of Battleship, if you know the game I play with my kids. I don't know what to ask for from the defendants. And so to the extent that there may be documents that weren't produced during the course of general discovery, I mean I can say that in the Pinnacle litigation, which is down in front of Judge Kincaid in Texas, that involves a hip that has not been on the market anywhere near as long as the Bair Hugger product has, but they have produced a hundred million pages of documents.

The Bair Hugger product has been on the market since 1987, when the Twins won the World Series the first time around, and we have 230,000 documents produced in this case, just a little over two million pages. So was their production robust and complete at the time of 2017? As officers of the court, I'm going to leave it to them to make that representation.

But what I do know and what is uncontroverted is since 2017, they have sponsored studies. We cite the Court to the Rio study. That is a pilot study that's underway in the UK right now. It came up at Reed's deposition, which was, I think, December of 2017. He talked about the study being undergone. And, of course, Reed, as far as we know, is going to be the real basis for their motion for reconsideration that comes in later today. They're sponsoring the guy. He's one of the main authors of the McGovern study. We know that they're having ongoing conversations.

The defendant's opposition papers don't contest the fact that there are in fact responsive documents that have been created since the close of discovery. They simply say we don't have to supplement. But that's not been the rule.

I mean back in, and I want to say it's, and I have a case about this because I was looking at it late last

night. There's a case in Minnesota because it used to be, I think it's *Carlson Companies v. Sperry*, but in the early '70's, it used to be that discovery was essentially what did the defendant know as of the time you filed your lawsuit? And the District of Minnesota in 1973 said that's not the rule really. It should be everything that you know not just, you know, discovery cut off the day that the plaintiff files the lawsuit but going forward. That's certainly not the rule now.

There's a duty to supplement discovery. And we have, and I brought if the Court would like to look at it, although, I assume not. And, again, I apologize, by the way, about the Court's practice pointers about wanting to know exactly what discovery responses we are bringing motions to compel on. I've got them all here if you would like to look.

But by way of brief example, you know, post-market surveillance. The plaintiffs have requested, you know, all documents relating to any articles that are published in medical journals regarding the safety or efficacy of the Bair Hugger, any documents reflecting meetings or conference calls about these kinds of articles. That's in some of our post-market surveillance. There's regulatory requests that were responsive and we talk about this with respect to the FDA letter. So we had document requests outstanding in

2016. We know from what was produced after the general causation hearing and after that process closed, we got a small production of what was provided to the FDA. It was not complete. We know it's not complete because we got additional documents in preparation for the Gareis trial last April that show a little bit more about what was provided to the FDA.

Suffice it to say it was not complete and did not include a single internal document that admits that every single study internal and otherwise admit that particles are increased over the sterile field whenever the Bair Hugger is turned to warm and that they have no evidence to refute that.

There's nothing provided to the FDA in those documents that say, hey, 3M does not contest the fact that the inside of these machines is filthy. They are prone to growing bacteria. They don't tell the FDA that. The entire volume of documents that we got, and I believe it's 143 documents from Susan Danielson's file. They're all about Dr. Augustine.

And, again, in the responsive papers, defendants, you know, they suggest that we're allies with Dr. Augustine. Obviously, Dr. Augustine's shadow casts long in this case. And, unfortunately, it has been a distraction for everybody. And we have said a number of different occasions as we

brought various motions that we wish that Dr. Augustine would be excused entirely from the MDL, and that if there is truly a product disparagement or some sort of business tort case, the defendants believe that Augustine is doing something they shouldn't, they should sue him. They should bring him to court or they should stop talking about it. But what they can't say, what they can't continue to say is that Augustine is actually behind everything here and that the plaintiffs are in fact allied with him.

Defendants, in their responsive papers, make much about independent researchers in the UK that's only partially funded by 3M doing this Rio study. Of course, every other time that we're in front of the Court, if there's somebody such as Augustine or someone else, the plaintiffs having done a CFD analysis, then the allegation is that the funding taints the entire results. They acknowledge that this Rio pilot study is something that they fund. It's my understanding that the funding has not been continued, but they acknowledge that these are prominent and important researchers.

THE COURT: Let me ask you so, obviously, you know, some of that information is quite obviously in the public record or you have access to it. What is it that you -- how would you describe other than generally just supplement, what is it you would describe as what you're

really looking for? And you can use as an example, and I don't mean it as an exclusive, but as an example the Rio study, what is it you're seeking?

MS. ZIMMERMAN: Well, so, for example, from the Rio study, to the extent that there are any preliminary results, we're limited to what is available on the Internet at this point because Dr. Reed's deposition was, you know, almost two years ago now. We knew that it was underway. We knew that it was funded by 3M. We know that it's looking specifically at this question about the impact of infection with forced air warming devices.

What I can see on the Internet is that they expected results to be released sometime around December of 2018, so in the last month. Nothing has been updated yet, and I'm not really surprised about that. It's holidays and all that. But it's a strange reason to suggest that 3M is paying money supportive of this kind of a study, and they're not getting any kind of preliminary results. And particularly because it is our understanding that 3M has declined to fund the remainder of the study after the pilot is completed. I don't know why that is, but we believe that there are documents that reflect 3M's thinking on that.

And, for example, we have some documents cited in our motion papers. 3M has been very involved in trying to keep various organizations by, for example, ECRI. The

internal documents say let's make sure that ECRI doesn't do their own study here. We want them to rely on us instead.

We know from the Sessler Olson study, that that was actually a study that was conducted by 3M executives over in the Netherlands. They found a couple of people to put their name on it. 3M wrote the entire thing. They got permission from Sessler to edit away because he was not sophisticated in the statistics.

So what we want to know with respect to Rio, with respect to ICOS is what is 3M's involvement in this? Because the documents that we do have show that they have had their hands deep in the science, deep involved in stopping studies from being published in terms of getting studies that were on the way to being published, edited, changing results with respect to the Netherlands study. There were different portions that 3M had removed from tables. I want to know that. Plaintiffs are entitled to that. That's what the discovery requests that we have served require or request. And because there is a duty to supplement and because we know that these things are out there, we request that 3M be ordered to do that supplement as plaintiffs would be required to do.

THE COURT: Okay. Let's assume for a second that the Rio study comes out tomorrow, and it's highly critical and very favorable on the science to the plaintiffs, how

would that get into evidence given that it's 2019?

MS. ZIMMERMAN: Well, that's a good question, Your Honor. I suspect that depending on what kind of production is made, there may well be -- and, I guess, to take a step back. I think the defendants really mischaracterized plaintiffs' motion here as a motion to reopen all the general discovery. I think that's really what Your Honor's question goes to. That's not what we've asked for.

What we've asked for is that they supplement the discovery responses that they provided thus far. It may well be, depending on what kind of additional documents or supplements are provided, that we bring a motion for leave or a motion to amend the scheduling order to allow us to conduct additional discovery. But plaintiffs have not requested a redo of general causation, a reopening of discovery in any way in this case.

And so if Rio comes out and it turns out that it is helpful to one side or the other, I suspect that the Court is going to hear about it either in the form of a motion or an exhibit to the motion for reconsideration or a motion for leave to conduct additional discovery. I will say that depending on what the motion looks like later this afternoon, I anticipate that there is going to be a motion to reopen discovery at least in some respect anyways because to the extent that there is new information, plaintiffs'

experts must be entitled to consider that and respond to it, if we are going to be looking at Daubert and general causation for 5,000 claimants.

To the extent that the defendant's position may well be they get to use new information but we don't get to respond, I don't think that that position finds any kind of grounding in the rules, but I guess we'll find out what their motion looks like later.

I will say that there is a number of different documents, and again, this is going to the issue about what other competitors know about, what other device companies know about because that duty of an expert is imposed on 3M. The heater-cooler units, and I don't know that Your Honor has heard a lot about the heater-cooler units. It's a different kind of a medical device that's used in an operating room, typically, in cardiac surgery. It both heats and cools the patient when they're on bypass.

The reason it's relevant to this case, our infectious disease doctor, Dr. Jarvis, said that mechanistically the problem that they discovered with the heater-coolers is the same problem that he sees with the Bair Hugger and that is two-fold:

One, the device has become essentially a reservoir of bacteria. That's uncontested in this case with respect to Bair Hugger. Their 30(b)(6) witness says, yeah, we don't

dispute that. These things get full of bugs, full of germs. They don't tell anybody about that, but that's a problem.

The second part, and the reason that ultimately lead to 12 different articles; and, ultimately, a recall of multiple different kinds of heater-cooler units is that the exhaust air from those heater-cooler units that sit in the operating room was blowing essentially over these water units where the bacteria was held and aerosolizing causing the bacteria to get into the air and ultimately into the surgical site.

Now, in the heater-cooler units because it was such a strange and rare bacteria, it was a mycobacterium chimaera, but they did a number of different studies and they found to a DNA level that it was in fact the same kind of bacteria that got from this unit in the hospital in the OR into the patient's heart in two different instances. And, ultimately, through a number of different studies, many of which mimic the studies that have done by the plaintiffs' experts in this case, they showed that is exactly what happened. It led to recalls of a couple of them. And the heater-cooler units now according to the CDC and FDA, they are recalled, and they have warnings to make sure that they do not disturb laminar air flow.

And I can show -- so this is the label of the bottom of the one of the heater-cooler units. In order to

avoid disturbances in the laminar flow area of the operating room, make sure that the heater-cooler unit is placed in such a way that the exhaust flow is not directed toward the operating field.

The reason that that matters is that they figured out through all these studies that these inanimate objects that have previously been considered essentially inert and not posing a risk to the patient, they hold bacteria, they blow bacteria, and it causes risk to the patient. Same exact thing here.

Now, Dr. Jarvis wasn't allowed to talk about that at trial, but these are relevant facts. And we know from some of the documents that have been produced that 3M is discussing the relevance of the heater-cooler units recalls with respect to the forced air warming. And when you add in what we know that Augustine knew in 1987 and 1993, and when they submitted their 510K to the FDA in 1996, that airborne contamination is a risk with this product.

We know that the manufacturers of other devices both in the forced air warming unit market and otherwise warn about this kind of thing. We know that 3M, well, their predecessors used to warn about it, but when they put that device into the operating room where patients are at a greater risk, they took the warning off, and they still don't explain why there's no warning today in January of

2019, even though their competitors warn about it.

So we know that there's additional discussion going on. And I would point the Court, again, to the ICOS. So that's the International Consensus on Prevention of Perioperative Infection I think is how it ultimately comes out, but we call it the International Consensus or the ICOS. 3M is a platinum sponsor.

The first time the group got together was 2013. They got together last summer again. Their main expert on orthopedic surgery is one of a handful of editors of the entire paper. Dr. Elgobashi's published report, our CFD expert, is cited in this paper.

Now, the ICOS, again, they recognize the theoretical risk posed by these products. They say that there are alternatives that can and should be used, but they're not at this point. They're saying they want more study but until the more study is done, they're not suggesting that everybody needs to stop using these.

We know that 3M is discussing it. We know that they're involved. We know that their previous CMO, Michelle Hulse Stevens, was at the first International Consensus, and she came back and she said, hey, guys, this issue is everywhere. Orthopedic surgeons are super concerned about particles in the operating room, and there is uniform agreement that forced air warming units increase the number

of particles.

Now, of course, we know that because Al Van Duren, their corporate 30(b)(6) witness, admitted as much. Every single study shows more particles when the Bair Hugger is used. So we know that they're talking about it. We know that these documents exist. Defendants don't even deny that they exist. They're just saying that they don't have to supplement and that's not what the law requires.

So we would request that the Court order that they supplement their discovery responses as required by the rules. And I'll stand down for now pending questions from the Court.

THE COURT: Okay. Thank you.

Ms. Young, before you begin, let me ask you a couple of questions. Number one, I had not, frankly, noted the briefing date of the motion for reconsideration but that's today, apparently.

MS. YOUNG: Yes, Your Honor.

THE COURT: And 3M will be moving to reconsider general causation, correct?

MS. YOUNG: Correct.

THE COURT: Will 3M be submitting new documents or testimony or disclosures by experts that have not been previously produced to this Court?

MS. YOUNG: No, Your Honor.

THE COURT: Okay.

MS. YOUNG: There is not, there is no -- we don't have access to and we don't know of any preliminary results from the Rio study, which Ms. Zimmerman is talking about. We'll be referring to published literature, the International Consensus statement from 2018, the gene studies, but no testimonial evidence, affidavits, new documents.

THE COURT: Okay. So I just want to make sure of this. Is there anything that you will be submitting in support of that motion that has not been either previously produced or publicly available?

MS. YOUNG: No.

THE COURT: Okay. All right. Go ahead.

MS. YOUNG: Your Honor, just a very brief setting, and I know Your Honor knows this from the extended hearing we had in the Axline case on the motion to exclude supplemental expert reports, but general causation discovery in this case refers not just to the general causation question of whether the Bair Hugger is capable of causing infection, but also covered regulatory issues, it covered voluminous documents that would go to 3M's knowledge, conduct. And so when we're talking about this general --

THE COURT: It's really case-wide discovery or omnibus discovery, if you will.

MS. YOUNG: Right. What we described as issues that cross-cut across the cases in the MDL. So that discovery closed on March 20th of 2017. And 3M had responded at that point to 200 requests for production, 30 interrogatories, and with quite significant oversight by Magistrate Judge Noel, we worked through an ESI protocol that covered 26 custodians. There was much debate about whether that should be expanded. Judge Noel ultimately said, no, 26 was the right appropriate number here.

We ran search terms, we checked, we double-checked, so this notion that there is this ongoing duty to supplement that discovery. And I see that Ms. Zimmerman brought today some manila folders with highlighted discovery requests, that has not ever been presented to us in that fashion. She named a couple.

But what plaintiffs are suggesting here is that we have some ongoing duty to supplement those 200 RFPs through some ESI process I assume because I don't know how else a company like 3M would be able to come up with a responsive set of information. So I think that request is well beyond what any duty to supplement that is contemplated in the Federal Rules.

Rule 26E talks about the requirements to supplement incomplete or inaccurate responses to material issues. I think we have two things that are in debate here.

One is when does that duty to supplement -- what does it relate to material that was created at the time of your original response and you later discover it and you produce it because you know you need to to make your response either accurate or complete, and that can happen if you perhaps had a set of documents in an ESI review that were tagged for further review, needed to be reviewed, inadvertently hadn't, you go through them and you role out a supplemental production. I think that happens frequently.

Then the idea here and what Your Honor was talking about with your question I believe is what has happened since March of 2017 and today? And is that really the information that plaintiffs are seeking? And if so, I think that brings us to the next question of is it material? Is it relevant to the issues in this litigation?

So, I think with respect to what is required by way of supplementation, we cited, and I apologize that we got it to Your Honor by way of letter, and it wasn't in our brief, but a string of cases that talks about the duty relating to information that is not about information that is gathered after, that we have to have some, the scheduling orders discovery deadlines have to mean something, especially in an MDL like this. They were designed to promote efficiency across the cases, and there simply can't be some ongoing duty for 3M to go through 200 RFPs.

And, again, as to issues that are not in the case, the reservoir of infection theory the Court has rejected because there's no scientific support for that theory. The failure to warn claim was not allowed in the Gareis case, so how 3M's internal discussions about a study are relevant and admissible to the design defect question in these cases is not a material issue. And plaintiffs haven't articulated why that would be the case.

And so, Your Honor, I also just want to say just briefly about what we did do. We not only produced that, but there in the declarations submitted in the report, you can see there were some supplemental productions. And so what we did was to the extent there were documents that were missed the first time either because they needed a further review, those were ruled out.

We also certainly understand our duty under Rule 26(a)(1), on initial disclosures to supplement with any material we intend to rely on, and I think that some of the cases that plaintiff cited talk about, you know, to avoid sandbagging, to be fair in litigation, that's exactly what those supplements would be designed to do. We're not going to try to show up at trial with a document that we have never produced. And then we also had the FDA information. Plaintiffs served a second set of discovery outside the close of general cause discovery, and we negotiated with

them and said we understand you want these documents. We think you're entitled to them, and we negotiated that.

So I think the casting this as a request for supplementation as opposed to reopening of general causation discovery, I don't think that's a fair characterization given the broadness of that and how it would essentially completely nullify the general causation discovery deadline and reopening that has been rejected at numerous times by this Court.

We, of course -- plaintiffs say 3M admits we would have information. Of course, a company like 3M involved in a 5,000 case MDL is going to have an active product line. It's going to have documents that would fall within 200 RFPs. We would never contend it didn't.

I think the question here is are we in violation of Rule 26 for failing to supplement that? And we contend no, because there's absolutely no evidence that anything we provided as of the general causation discovery deadline is either incomplete or inaccurate in a material respect. And then the other question I think goes then more to the very specific request that they're making and that's in which fall into three categories.

We have, first, the Rio study. As plaintiffs point out, 3M committed to a partial funding of the first phase of that. We provided that funding. We are not and do

not have access to any preliminary results. We don't know anything other than what's on the Internet about the Rio study, and so plaintiffs' suggestion that what internal folks at 3M might have said about that study, we don't see how that is relevant to any of the issues in this case.

On the FDA letter, plaintiffs concede that we produced the documents that were responsive. There is, you know, that letter was not ultimately admitted in trial, and any more information or discussions 3M made have had about that, I don't believe there's any ongoing duty to supplement that.

Plaintiffs also make an absolutely erroneous statement that 3M admitted during the Daubert hearings that the letter was the result of a lobbying campaign. That just isn't true. That's not what the transcript says. We provided information to FDA. FDA took information from us from other manufacturers of forced air warming devices, from health care providers and that's right on the face of their letter. So the notion that they're still going after this idea that somehow 3M manipulated the FDA and controlled that letter is just an unproven premise that's been brought up many times in litigation.

THE COURT: Well, the letter was not allowed into evidence, correct?

MS. YOUNG: Correct.

THE COURT: At the Gareis trial. And I'm assuming there wasn't any, maybe there was, evidence relating to actions the FDA either took or didn't take other than the 510(k) clearance?

MS. YOUNG: Actually, the Court was very restrictive, and no FDA clearance came in -- the letter or otherwise.

THE COURT: Okay.

MS. YOUNG: And then, Your Honor, we have the International Consensus meeting. So that is, Your Honor knows they are the premier organization globally. They have 800 delegates who are looking at evidence of issues. One of the things that they were asked to reconsider at their second meeting was the question of whether there's any evidence that forced air warming causes or contributes to surgical site infections. They responded with 93 percent consensus, a strong consensus that there is no evidence of that.

3M was a platinum sponsor. There are 55 sponsors to that meeting. They're all listed in the first preamble portion of that report. Mike Reed, one of the authors who Your Honor has heard about involved in some of the UK research relating to the Bair Hugger was part of that process, as was Dr. Mont. These are the leading orthopedic surgeons, microbiologists, people that understand

periprosthetic joint infections. And so we have that information. We'll cite the publicly available information.

They also include their rationale, all the evidence that they looked at, evidence that is available to -- they certainly are aware of the Elghobashi published article that plaintiffs cite to. So how 3M's internal communications about the fact that that group is meeting have any relationship to this case, we don't think plaintiffs have articulated that, and they can have equal access to the publicly available information about the ICM.

And so, Your Honor, plaintiffs have not shown that 3M is in violation of Rule 26(e) across the board, and what they're asking would be equivalent to reopening general causation and taking away any finality that that bifurcation order has had.

We also note, and it's in our papers, I won't belabor this, but plaintiffs haven't done any supplementation other than in the bellwether case specific, and they were ordered to answer some specific discovery and there are plaintiffs' firms that have never complied with that either.

So it's our position, Your Honor, that they haven't met what would be the requirement under Rule 26(e) to show that our answers at the time they were made were incomplete or inaccurate in a material respect, and they

also have not made any effort to show how good cause would be shown to change what would otherwise be a Rule 16 scheduling order issue.

THE COURT: Let me ask you a couple of other questions. And I don't know that this matters, but does 3M or its lawyers have in place some system or some practice such that documents that are created or obtained after March 20th of 2017, if they undermine render inaccurate or incomplete prior discovery responses get somehow flagged for review?

MS. YOUNG: You know, Your Honor, we certainly have ongoing holds for litigation, but I think you're talking about information that would have been previously available or all of it?

THE COURT: No, I'm specifically asking about, well, first of all, let me say this about information that was previously available as of the time of general causation discovery. I don't hear anything that says as of March 20 of 2017, other than as supplemented thereafter, that 3M's production was incomplete.

MS. YOUNG: Correct.

THE COURT: And I'm assuming but I should ask you as an officer of the court, do you have any information that would suggest that that production for documents that existed and were in 3M's possession or subject to its

control in March 20th of 2017, was somehow not produced?

MS. YOUNG: I do not have information that there were any inaccuracy in the information provided on that date.

THE COURT: Or incompleteness?

MS. YOUNG: Or incompleteness. We have the 26 custodians search terms, we've run and rerun, double-checked against that and have rolled out supplements where appropriate.

THE COURT: Okay. And as to documents that were either created after March 20th of 2017 or came into the possession or control of 3M after March 20th, 2017, and as I say, I don't know if it's relevant, I should say germane to this issue, but is there a process by which 3M or its attorneys review that information or those documents?

MS. YOUNG: In terms of a systematic process, Your Honor, I'm only thinking that the way we would approach discovery generally would be the ESI collection and searching. And so while folks are on hold, that hasn't all been pulled into my understanding and run through search terms. Of course, we're in touch with key witnesses there, and to the extent any of them were to say, look, what about this? I found this file next to my desk after we had spoken so much about the Bair Hugger, we would absolutely be tracking that and evaluating and making a production if that

were required.

I'm not trying to dodge your question, but it's a little bit hard given the way that we ensure we're finding information with the corporation, and so I could say on an ad hoc basis given the people we're in touch with, we absolutely would have them continuing to forward things to us or bring things to our attention.

THE COURT: Right. Now, I think it's an easy call in a sense to say that to the extent that you have documents that have not been produced, that you intend to rely upon, obviously, that will be an issue that the Court will have to look at, you know, so that there is no -- clearly, 3M is not going to put a document on its exhibit list. Clearly, 3M is not going to be allowed to put a document on its exhibit list that it hasn't produced in discovery absent some highly exceptional circumstances.

So I worry less about the issue of trial by ambush than what I think is motivating the plaintiffs which is how do we know that there aren't documents that would be helpful to the plaintiffs that 3M isn't just concealing? And I think the answer to that is partially that Magistrate Judge Noel supervised that process regarding custodians and search terms up to March 20th of 2017.

But then the question mark I think they have is and since then what? How would they ever know that there's

information that is material that would show the prior document request productions have been inaccurate or incomplete? That's what I think the nub of their issue is, and I don't know that it necessarily matters, but can you respond to that rather rambling question?

MS. YOUNG: I think what I'm, so what I'm struggling with a little bit is the idea that there's a document that existed as of March 2017 that wasn't provided and would be necessary to make a response wholly complete or accurate or that there would be information created after that that looking backward would somehow make the response at that time inaccurate or incomplete?

THE COURT: The latter.

MS. YOUNG: And I think there what we're struggling with that is we have 200 RFPs, 30 'rogs, and absolutely no indication -- and the Court's significant narrowing of the issues in this litigation. So to suggest that it's like a needle in the haystack. I know Ms. Zimmerman pointed out a single, a couple of the things she pointed to also are issues that the Court has narrowed and are not in the case, so the notion that we would even know what it is we're looking for without some more specific guidance here.

This request too was made, I mean to the extent there was any meet and confers on it, it was the last

sentence of a number of letters that essentially said, and we remind you, 3M, of your ongoing duty to supplement things that are attained and/or generated after the close of fact discovery. I mean there has been no effort to actually narrow in on, I think, what Your Honor is saying perhaps there is, you know, some narrow subset, but the approach here was approved by the Court, was designed to get us through a very significant portion of the discovery in this MDL.

THE COURT: Okay. Thank you, Ms. Young.

MS. YOUNG: Thank you, Your Honor.

THE COURT: Ms. Zimmerman?

MS. ZIMMERMAN: Yes, Your Honor, if I could, I am compelled to start with to the extent that defendants continue to represent or argue that the issues in this entire MDL have been narrowed because of what happened in Gareis, that is just inaccurate. And it's, frankly, a misstatement of what Judge Ericksen said in the Axline Order on the motion for a judgment as a matter of law.

She rejected expressly their argument that because in Gareis certain consumer protection claims were out that they were then out for Axline and every other case. She said expressly in her order that is not the case.

So there are asserted by 5,000 people failure to warn claims, negligence claims, design defect claims, all

sorts of claims that have not been disposed of on an MDL-wide basis. So as a preliminary matter, those are live claims. We have discovery requests outstanding, the Federal Rules require that they supplement.

Now to the extent that counsel has just represented that Judge Noel has carefully supervised the discovery in this process, that's just not accurate. Judge Noel was certainly involved in the beginning of the parties kind of trying to work together with respect to these requests for production of documents and that was in between April and June of 2016.

We also had a stipulated order entered by the Court with respect to ESI document collection and that sort of thing. And I have to check back, my memory is a little fuzzy, but it was end of 2016, beginning of 2017, defendant said, hey, I know that there's an order saying this is how I have to collect it. It's not working the way we agreed to do it, and so we just want to do it the old-fashioned way.

And despite the fact that there was an agreement and despite the fact that it was reduced to an order, the defendants were not required to continue to collect documents the way they agreed to do so, and the way the Court ordered it. Now, the Court ultimately blessed that, but it is not true to say that Judge Noel supervised this all the way through March of 2017.

You know, there's a bit of argument both in the responsive briefing and otherwise about plaintiffs' ongoing attempts to do reopening discovery and really what they're alluding to in their footnote is plaintiffs' attempts to serve subpoenas on Dr. Minkowitz, who is in Chicago. He's an editor of a paper or a journal where one of defendant's experts claims to have submitted and had published a peer review journal based on the deposition testimony that we obtained after the close of discovery, and we couldn't bring the motion until we got him to misrepresent and we believe actually outright lie about the case, the status of his peer review paper. Once we had that representation under oath, we served a subpoena and we sought the discovery.

There was a motion in front of Judge Noel. Judge Noel reduced to an Order a finding that Dr. Abraham's paper was not subject to peer review. Plaintiffs attempted to impeach Dr. Abraham on the stand with that order. It was excluded. The Order was excluded on hearsay grounds. The Order of Judge Noel was excluded on hearsay grounds.

So, plaintiffs, yes, we have tried to get that discovery. We think we're entitled to it. We still think we're entitled to it. We haven't been able to impeach a witness that was put on the stand with an Order of the Court. We think that that's outrageous.

Your Honor asked some questions about how do we

know, and I made probably a terrible analogy with respect to the game of Battleship I play with my nine year old, but that is the nature of plaintiffs' work, right, and I understand that. But what we do know with respect to defendants, the completeness of defendant's production as of March 20th of 2017, which Your Honor asked about, we know it wasn't complete at least with respect to communications with the FDA.

And I would point Your Honor and counsel specifically to the PowerPoint presentation that was provided to the FDA by lobbyist counsel in DC. The PowerPoint presentation itself is dated March 2nd of 2017. It was not produced to plaintiffs until advance of the Gareis trial. That appears at Bates range 3M BH02326976. So we know it wasn't complete. We know it wasn't complete.

And the other thing that matters about that is in that PowerPoint, they detail a number of different concerns that they're getting in. They're getting complaints from customers. They're getting concerns from orthopedic surgeons, and that's part of the basis for their Complaint to the FDA, and they say, hey, please weigh in on this and tell Augustine to stop making stuff up. That's really the basis of this. There's no medical studies that are provided to the FDA. None of that is on the index of materials, no internal documents, no depositions. So --

THE COURT: But a lot of what you seem to be raising or asking me to do is somehow it all has the quality of second guessing what's already been decided by either Judge Noel or Judge Ericksen. And in case it's not clear, I'm not going to do that.

So maybe the best way to get at this is would you describe for me what you're asking me to order 3M to do?

MS. ZIMMERMAN: Sure, Your Honor. We think that at a minimum the three issues that have been crystalized as much as we can in our papers and again today during argument, is an order to supplement any documents that they have internal or otherwise that fall within the previously served discovery responses with respect to Rio, with respect to ICOS, and with respect to the FDA. And the reason all that matters is that it all keeps coming back.

Sure, the FDA was mostly out of the Gareis trial. Again, that doesn't mean that it's going to be out of Trombley, if that's tried in May or whatever other trials come down the line, whether in this Court or elsewhere around the country. So we're entitled to do that discovery. We're entitled to get that discovery.

We know from the representations from counsel that the FDA did get involved in this at the request of 3M. We know from some of the documents that have been produced. We don't know if they're complete. We do know that it was a

lobbyist from in DC that directed a lot of those efforts on 3M's behalf.

Your Honor may be familiar from your experience in private practice about the way the FDA normally works when there is something like this; usually there's a public meeting, usually there's a detailed list of every single thing that was concerned, considered, usually there's testimony and all these sorts of things. None of that happened here.

What we know after the close of discovery is that there were documents generated prior to the close that were not produced. We know that they were not produced until after our general causation and Daubert orders were obtained. I guess it was before we got the order but it was after the arguments, after the briefing, then they produced the documents at the beginning of November of 2017.

So we know the productions weren't complete in March. We know the documents existed then. We know from the PowerPoint they were getting complaints in from customers. They were getting questions from orthopedic surgeons? What did they do to respond? All of that is responsive to plaintiffs' requests.

So at a minimum we would ask for the Rio study and any documents that talk about that, the ICOS studies, and anything that demonstrates what 3M's involvement has been

with respect to the 2018 ICOS and their internal discussions. Sure, they're -- I'm sure that they're happy to stipulate as Your Honor kind of questioned. They're not going to introduce into evidence a document they haven't previously produced. Those aren't the documents I want. I want the documents they don't want to give me, right? I mean I want the seven documents that I care about that I can try my case in front of a jury and they're going to be outraged.

I know some of those documents. I've seen some of those documents. I've focused group some of those documents. I know juries are outraged by it. The question is how do we get what they know? How do we get what we know their competitors know and acknowledge? This is a huge product. They make a ton of money. We are in their back yard begging that the rules be enforced.

One final note, and I grabbed the defendant's answers and objections to the plaintiffs' second interrogatories, and this is not before the Court, but it is dated March 31st of 2017. And I only want to put this up to show that the defendants in fact also contemplated that they were going to have to supplement. So at the end of -- so what do they say in one of the answers? "Defendants will respond further after the time required for expert witness disclosures in accordance with Rule 26 and the Court's

operative scheduling order." And this is, you know --

THE COURT: Well, but that's appropriate. It's a contention interrogatory.

MS. ZIMMERMAN: Yes, absolutely, absolutely. But they understood that there are ongoing duties to supplement but they don't stop on March 31st or March 20th of 2017 as they would suggest is the law.

THE COURT: Well, I understand your point. And I'm not so sure that demonstrates it because I think that's really getting at a different issue. But, you know, there's no question that there's a duty to supplement. The question is whether or not there is an obligation or they failed is probably the better way to put it to meet that duty in this case with respect to general causation.

So, okay, anything further Ms. Zimmerman?

MS. ZIMMERMAN: I don't think so.

THE COURT: Ms. Young, are you champing at the bit to say anything else?

MS. YOUNG: One very brief thing, Your Honor.

THE COURT: Okay.

MS. YOUNG: And that is just going back to the idea that 3M has lobbied the FDA, the FDA was well aware of this issue. Scott Augustine and his attorney filed anonymous MedWatch reports that parroted the complaints in this cases by the hundreds, I believe. So the idea that the

FDA wasn't aware of Scott Augustine's advertising, the litigation, and everything that was going on is just not an accurate statement.

THE COURT: Okay. Thank you. All right. It is 11 o'clock. I'm going to take a recess and look at my notes, look at a couple of things and then we'll come back.

It's been my practice, as you know, as you all know, to try and rule on things of this nature quickly and from the bench because I think it does the parties more service that way than to perhaps take 30 days or whatever it takes to get out a very, you know, lengthy and detailed memorandum.

So I'm going to go look at this, and we'll be back on the record in 15 minutes or 15 minutes after 11. Okay? All right. Court is in recess.

(Short recess at 11:01 a.m.)

(In open court at 11:18 a.m.)

THE COURT: Good morning. Be seated.

All right. We are back on the record in the Bair Hugger MDL number 15-2666. I am going to go ahead and rule on the motion to compel supplementation on the record. That will be followed up with an Order that just says, "For the reasons stated on the record," et cetera, et cetera, et cetera. So here is my ruling and rationale:

I am going to deny the motion to the extent that

it requests me to compel the defendants to undertake a general supplementation of its responses to all of the discovery in this case. I am going to grant some specific supplementation, which I will outline later. But let me just say my rationale for these rulings is as follows:

First of all, the discovery on general causation by Court Order, Pretrial Order 17, which is docket number 175, was closed on March 20, 2017. Since that date, the defendant has provided supplementation to its discovery on nine occasions. The support for that is the Declaration of Benjamin Hulse, paragraph 1, which is docket number 1715.

I will note that the plaintiff, according to Mr. Hulse's declaration and I have no basis to think otherwise, the plaintiff has not supplemented its discovery responses since March 20, 2017, on the question of general causation. However, has provided additional or supplemental information as to bellwether plaintiffs, quite obviously.

You know, the duty to supplement under Rule 26(e) is clear and definite, but it's a limited duty. And so that duty under the express terms of the rule is simply to supplement with, well, to supplement either a document request or an interrogatory answer or a request for admission, if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information is not otherwise

been made known to the opposing party during the discovery process or in writing.

And so that discovery duty to supplement is to correct material inaccuracies or material incompleteness, and I am aware of the cases that say it had to be materially incomplete or inaccurate at the time that the discovery response was made. However, I believe the better rule is that after acquired evidence that might call into question the continuing accuracy or completeness of the discovery response should also be subject to supplementation.

So on the question, I think, of what the defendant calls the refresh or the generalized supplementation, that is not, I am not familiar with anything that says that is typically undertaken. It is certainly not warranted in light of the defendant's representations to this Court, and there is no evidence before me that gives me any basis to believe that as a general rule the defendant's discovery responses are incomplete or inaccurate. And I think ordering it would not only be burdensome to the defendant, it would in fact undermine the orderly process that has been the subject of the Court's Pretrial Orders. And it would effectively nullify the Court's Pretrial Order 17 that had a cutoff date.

So that result in my view is consistent with Judge Ericksen's Pretrial Order. It's consistent with Rule 26(e),

and the cases from this district including the case cited by the defendant's *Promotional Marketing Insights*, which is found at 212 Westlaw 13028115.

Turning to specific supplementation, let me -- I'm going to make some general comments that are going to seem inconsistent with what I've ultimately ruled. I don't believe there is any evidence before me that any of the productions with respect to the three specific matters were incomplete or inaccurate in any material way either at the time made or even now. But at the same time, I am mindful that the plaintiff always suffers from a little bit of an information deficit in that regard.

So the FDA communications prior to the August 2017 letter, the defendant's production was made after August 30th of 2017, and the defendant certified that at the time it was made it was complete, and the letter was excluded from the Gareis trial even though I believe the defendants had wanted to put it in.

That notwithstanding, and I am skeptical that any of the discovery supplementation I'm about to order will lead to the discovery of admissible evidence or will itself be admissible but that's not for me to decide.

So I am going to order the defendants to supplement their document production to include any further communications with the FDA on the limited topic of the

August 30th, 2017, letter. So that's as to the FDA.

As to the International Consensus, again, it appears to me that this Consensus meeting is occurring post cut-off of the discovery, and if the FDA letter isn't going to come in, it's hard for me to envision how a report or publication of the International Consensus would be admitted at a subsequent trial.

That notwithstanding, I will order the defendants to produce to the plaintiff any communication with the International Consensus group from January 1, 2018, to the present, and any internal discussion of the International Consensus group that bears on the topic of whether the Bair Hugger Forced Air Warming System is capable of causing any of the infections which are alleged in this case. So, in other words, on the topic of the general causation. And, obviously, it goes without saying that it's by no means clear that that will result in the production of any documents.

The last item is the Rio pilot study. Again, I don't have evidence as to which document request this particular request is related to, and I'm skeptical of its ultimate admission or relevance. Having said that, I am going to order the defendant to produce the same materials with respect to the Rio pilot study that I just ordered with respect to the International Consensus, and that is to say

any communications with the pilot study group since the last production of documents by 3M, and any internal documents regarding the Rio pilot study that bear on the issue of general causation.

All right. Let me begin with Ms. Zimmerman, do you have any questions or is there anything you wish to call to my attention about that ruling?

MS. ZIMMERMAN: Maybe one question, Your Honor. When you order that the production of communications essentially with the ICOS and/or the Rio pilot study, is that intended to include essentially the authors or just -- honestly, I don't enough about these particular organizations to know if they have a central clearing house.

THE COURT: Nor do I. My intention is not to order communications with the authors per se except to the extent that that communication is undertaken in their capacity as a member of that group.

MS. ZIMMERMAN: Okay.

THE COURT: Does that make sense?

MS. ZIMMERMAN: So if it's communication with the person --

THE COURT: On the topic --

MS. ZIMMERMAN: On the topic of the ICOS.

THE COURT: Yeah, or in their role as an ICS member.

MS. ZIMMERMAN: Okay. I think that's the only question I have.

THE COURT: Okay. Ms. Young, other than perhaps a little bit of disappointment or consternation, do you have anything that you feel I should hear from the perspective of the defendants?

MS. YOUNG: No, Your Honor.

THE COURT: Okay. Very well. We will get an Order out today or tomorrow at the latest that simply embodies this without further discussion of the rationale. That Order when it's issued will start the clock for an appeal of that order to Judge Ericksen. Okay? All right. Thank you both. Court is in recess.

(Court adjourned at 11:31 a.m.)

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REPORTER'S CERTIFICATE

I, Maria V. Weinbeck, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: *s/ Maria V. Weinbeck*

Maria V. Weinbeck, RMR-FCRR